



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms (ID 3017, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2012.2853](https://doi.org/10.2903/j.efsa.2012.2853)

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2012). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms (ID 3017, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006*. European Food Safety Authority. the EFSA Journal Vol. 10(8) No. 2853 <https://doi.org/10.2903/j.efsa.2012.2853>

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms (ID 3017, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms. The food constituent that is the subject of the health claim, a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079, is sufficiently characterised. The claimed effect which is proposed for further assessment, defence against pathogenic gastro-intestinal microorganisms, is a beneficial physiological effect. The proposed target population is the general population. No human intervention studies which investigated the effect of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 were provided. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms.

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¹ On request from the European Commission, Question No EFSA-Q-2012-00205, adopted on 28 June 2012.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms (ID 3017, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(8):2853. [16 pp.]. doi:10.2903/j.efsa.2012.2853. Available online: www.efsa.europa.eu/efsajournal

KEY WORDS

Lactobacillus rhamnosus CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* CNCM I-3470, *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079, gastro-intestinal pathogens, health claims.

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of health claims in relation to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms. The scientific substantiation is based on the information provided by the competent Authority of France for further assessment of this claim.

The food constituent that is the subject of the health claim is a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079. The Panel considers that the combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 is sufficiently characterised.

The claimed effect, which is proposed for further assessment, relates to defence against pathogenic gastro-intestinal microorganisms. The proposed target population is the general population. The Panel considers that defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.

No human intervention studies which investigated the effect of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 were provided. The Panel considers that, in the absence of evidence for an effect of the combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 in humans, the studies provided on the effects of individual constituents cannot be used for substantiation of a claim on the combination. The Panel considers that no conclusions can be drawn from the references provided on the individual strains for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ in which the Panel concluded that the data available were not sufficient to characterise a combination of *Lactobacillus helveticus* CNCM I-1722, *Lactobacillus rhamnosus* CNCM I-1720, *Bifidobacterium longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010), EFSA received additional information from the competent Authority of France for further assessment of this claim. The information provided in the framework of further assessment for the health claim which is the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 3017)

The food constituent that is the subject of the health claim is a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079.

The formulation, which is the subject of the claim, contains the bacterial strains in a ratio of 1:1:1 in the form of lyophilised powders with a total amount of bacteria per capsule of 5×10^9 CFU. The amount of *S. cerevisiae* var. *boulardii* is 125 mg (corresponding to 2.5×10^9 CFU) per capsule.

The strain *L. rhamnosus* CNCM I-1720 is also known as *L. rhamnosus* R0011. A culture collection number from the French National Collection of Cultures of Microorganisms (CNCM I-1720) was provided. The CNCM is a restricted-access non-public collection which has the status of an International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of *L. rhamnosus* CNCM I-1720 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile) and genotypic (DNA-DNA hybridisation, 16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, strain-specific PCR, RAPD, PFGE) methods, were provided in the application for further assessment and in the accompanying references (Roy and Ward, 2004; Verdu et al., 2008; Yeung et al., 2002). The Panel considers that *L. rhamnosus* CNCM I-1720 is sufficiently characterised.

The strain *L. helveticus* CNCM I-1722 is also known as *L. helveticus* R0052. A culture collection number from the CNCM, I-1722, was provided. Data on the identification and characterisation of *L. helveticus* CNCM I-1722 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile) and genotypic (DNA-DNA hybridisation, 16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, species-specific PCR, AFLP, MLST, RAPD, PFGE) methods, were provided in

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

the application for further assessment and in the accompanying references (Naser et al., 2006; Verdu et al., 2008). The Panel considers that *L. helveticus* CNCM I-1722 is sufficiently characterised.

The strain *B. longum* subsp. *longum* CNCM I-3470 is also known as *B. longum* R0175. A culture collection number from the CNCM, I-3470, was provided. Data on the identification and characterisation of *B. longum* subsp. *longum* CNCM I-3470 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile, antimicrobials resistance pattern) and genotypic (16S rRNA gene sequence analysis, elongation factor *tuf* gene sequence analysis, RAPD, PFGE) methods, were provided in the application for further assessment and in the accompanying references (Mattarelli et al., 2008). The Panel considers that *B. longum* subsp. *longum* CNCM I-3470 is sufficiently characterised.

For *S. cerevisiae* var. *boulardii* CNCM I-1079 a culture collection number from the CNCM, I-1079, was provided. Data on phenotypic (morphological and biochemical analyses) and genotypic (RFLP analysis using a yeast DNA transposon probe for hybridisation, and PFGE and PCR delta sequence analysis) characterisation of *S. cerevisiae* var. *boulardii* CNCM I-1079 were provided in the application for further assessment. The Panel considers that *S. cerevisiae* var. *boulardii* CNCM I-1079 is sufficiently characterised.

The Panel considers that the food constituent, a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 3017)

The claimed effect, which is proposed for further assessment, refers to “helps to fight against gastro-intestinal (GI) pathogens”. The proposed target population is the general population.

The presence of pathogenic micro-organisms in the gastro-intestinal tract (e.g. viruses and bacteria) may lead to the development of gastro-intestinal infections. Defence against pathogenic gastro-intestinal microorganisms may protect against the development of gastro-intestinal infections.

The Panel considers that defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 3017)

The references provided in relation to this claim included human intervention studies, meta-analyses, animal studies, *in vitro* studies, publications on characterisation aspects and one review paper.

The human, animal or *in vitro* studies provided investigated the effects of *S. cerevisiae* var. *boulardii*, the effects of individual bacterial strains or pairs of bacterial strains, which are part of the food constituent that is the subject of the claim, or combinations of microorganisms other than the combination of strains that is the subject of the claim.

No human intervention studies which investigated the effect of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 were provided.

The Panel considers that, in the absence of evidence for an effect of the combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 in humans, the studies on the effects of individual constituents provided cannot be used for substantiation of a claim on the combination. The Panel

considers that no conclusions can be drawn from the references provided on the individual strains for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed for further assessment relates to defence against pathogenic gastro-intestinal microorganisms. The proposed target population is the general population. Defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of a combination of *L. rhamnosus* CNCM I-1720, *L. helveticus* CNCM I-1722, *B. longum* subsp. *longum* CNCM I-3470 and *S. cerevisiae* var. *boulardii* CNCM I-1079 and defence against pathogenic gastro-intestinal microorganisms.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00205). The scientific substantiation is based on the information provided by the competent Authority of France for further assessment of this claim (available at: <http://www.efsa.europa.eu/en/topics/topic/article13.htm>).

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Yeung PSM, Sanders ME, Kitts CL, Cano R and Tong PS, 2002. Species-specific identification of commercial probiotic strains. *Journal of Dairy Science*, 85, 1039-1051.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁵ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁶

Foods are commonly involved in many different functions⁷ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁵ OJ L12, 18/01/2007

⁶ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁷ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the

requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Health claims related to a combination of *Lactobacillus rhamnosus* CNCM I-1720, *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *longum* CNCM I-3470 and *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
3017	A combination of <i>Lactobacillus rhamnosus</i> CNCM I-1720, <i>Lactobacillus helveticus</i> CNCM I-1722, <i>Bifidobacterium longum</i> subsp. <i>longum</i> CNCM I-3470 and <i>Saccharomyces boulardii</i> CNCM I-1079	The food constituent helps to fight against gastro-intestinal (GI) pathogens. The presence of pathogenic microorganisms in the GI tract may lead to the development of GI infections like diarrhea from different etiology (antibiotic associated diarrhea, traveller's diarrhea, acute diarrhea). Indeed, antibiotic treatments, change in dietary habits when travelling, or hospitalization can lead to GI infections accompanied with diarrheas.	Defence against gastro-intestinal pathogens
	<p>Conditions of use</p> <p>The recommended dosage is two to four capsules per day. Each capsule contains 5*10⁹ CFU of bacteria and 125 mg of <i>Saccharomyces boulardii</i> (corresponding to 2.5*10⁹ CFU at manufacturing).</p> <p>To reinforce the intestine against intestinal traveller's disorders, take for three to five days before departure and while away.</p> <p>General population, including travellers to developing countries, who are a high risk population for the development of diarrhoea (traveller's diarrhoea mainly caused by bacteria; <i>E. coli</i> is the pathogen most frequently isolated).</p> <p>The percentage of each bacteria strain is 33.3%, under the form of lyophilised powders (total amount of bacteria is 5*10⁹ CFU per capsule). The amount of <i>Saccharomyces boulardii</i> is 125 mg per capsule (corresponding to 2.5*10⁹ CFU at manufacturing).</p> <p>The finished product is commercialised as a capsule under the brand name Protecflor.</p>		

GLOSSARY AND ABBREVIATIONS

AFLP	Amplified fragment length polymorphism
CFU	Colony forming units
CNCM	Collection Nationale de Cultures de Microorganismes, France
DNA	Deoxyribonucleic acid
MLST	Multi-locus sequence typing
PCR	Polymerase chain reaction
PFGE	Pulsed field gel electrophoresis
RAPD	Randomly amplified polymorphic DNA
RNA	Ribonucleic acid